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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,387	06/15/2000	Muthiah Manoharan	ISIS-4390	9395

7590 02/07/2003

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EXAMINER

MCGARRY, SEAN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 02/07/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/594,387

Applicant(s)

MANOHARAN, MUTHIAH

Examiner

Sean R McGarry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-19,27-29,32,39-43,46,53-57 and 311 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,2,5-19,27-29,31,32,39-43,46 and 53-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/25/02 has been entered.

Applicant has addressed the examiners concerns of applicants IDS filed 2/10/2000 by stating in footnote (2) that at the time it was not required that a copy be supplied. It was requested that applicant provide the examiner a copy of the requirement at the time the IDS was filed since the examiner has access to only the latest versions of the MPEP. It is noted that applicant has repeatedly refused to provide that which was requested and further has not provided the copies of all patents, publications, applications or provide citations of that relied upon in an application, for example, as required by 37 CFR 1.98(a)(2)(iii), for example. (Applicant asserts that the Rule 1.198 differed at the time of filing but has refused to provide evidence and the examiner therefore applies the Rule 1.98 before him) Those applications cited and not yet considered are not available for the examiner to review at the time of the instant Official Action, have not been made available by applicant, do not comply with 37 CFR 1.98(a)(2)(iii) and have therefore not been considered.

Claims 1, 2, 5-19, 26-29, 31, 32, 39-43, 46, and 53-57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 09/334,130. Although the conflicting claims are not identical, they are not patentably distinct from each other because of those reasons set forth in the provisional rejection in the Official Action mailed 10/3/01. It is noted that applicant has requested the provisional rejection be deferred until indication of allowable subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 7-19, 26, 27, 43, 46, 53 and 57 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons set forth in the Official Action mailed 7/30/02.

Applicant disclosure does not describe an adequate number of species of arylpropionic acids and protein, serum protein, vascular protein, cellular protein combinations such that one in the art would recognize that applicant was in possession of the full scope of the claimed invention. The invention is specifically drawn to oligomers conjugated to an arylpropionic acid that interacts with a protein in general and

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then is drawn to narrower embodiments. The instant specification does not provide one in the art what structural features, for example, of an arylpropionic acid allows binding to proteins in general and more specifically to different specific serum and vascular proteins. One in the art is not apprised of what structures would be included in the vast array of potential proteins that may bind to an arylpropionic acid for example. One in the art would not have known based on the instant specification what structural features would be predictive and descriptive of a protein that would bind to arylpropionic acids as disclosed for those arylpropionic acids and albumin, for example. The instant specification has disclosed only specific arylpropionic acids that bind to albumin. From this disclosure, one in the art would not recognize that the structural features that allow binding of a vast array of arylpropionic acids to a wide array of proteins, serum protein, or vascular protein have been adequately described. One in the art would not recognize the disclosure of the limited number of species is representative of the genus claimed. Although applicant has "disclosed the genus of arylpropionic acids" by a general statement that the genus is included, the disclosure of what arylpropionic acids that possess the attributes (eg chemical properties or specific structures) that are required for the instant invention (those attributes that allow binding to a protein, serum protein or vascular protein , for example) have not been described. Applicant argument is based on the argument that the examiner has not provided a number of species that would be representative of the genus claimed and that the examiner has not provided evidence for his position. It is noted that the rejection of record indicates that one species is inadequate and further the arguments provided in the rejection of record an

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those provided by the by the examiner above and in the Official Action mailed 7/30/02 and the Advisory Action mailed 10/29/02 provide reasons for this assertion. The determination of a specific number would not be proper since the issue at hand is "is the one species demonstrated in the instant specification adequate to describe the genus claimed?" Applicant has not specifically addressed the specific arguments of record but only asserts that a number is needed. For example applicant has not provided arguments or evidence that the one species demonstrated in the instant specification is all that one in the art would require to describe and represent the genus claimed. It is the position of the examiner that, in the instant situation, the number of species required in more than one for the reasons set forth above and of record.

Claims 1, 2, 5-19, 21-29, 31, 32, 34-44, 46, and 48-57 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for that scope indicated in the previous Official Action mailed 10/3/01, does not reasonably provide enablement for the scope claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is maintained for those reasons set forth in the Official Action mailed 7/30/02.

Applicant's arguments filed 1/22/02 and 11/25/02 have been fully considered but they are not persuasive. Applicant has argued that the rejection of record does not provide evidence indicating a reason to doubt the enablement of the instant invention and that the arguments presented in the rejection has failed to provide evidence.

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Applicant has argued that the rejection appears to require an example for every arylpropionic acid. The rejection does not so require but discusses the failure of the specification to provide adequate examples or guidance that would correlate to the practice of the scope of the invention instantly claimed without undue trial and error experimentation. Applicant argues that the rejection of record has not established why some arylpropionic acids are enabled and some are not. It is noted that the rejection provide detailed reasoning why the scope of the invention has been found to be not enabled. It is noted that applicant arguments do not address the specific arguments set forth in the rejection such as those in section (c.) and (d.) of the rejection. Applicant has argued two of the three reference cited in section (d) of the rejection of record (Kleinberg and McClure) These reference do demonstrate that at the time of filing it was not predicable what drugs or compounds or proteins , for example would bind to a desired protein. The references of record support the assertion of the examiner that, in general, one in the art would not expect that arylpropionic acids would predicatably bind to any particular protein without a teaching of a binding site specific for an arylpropionic acid. The instantly rejected claims are so broad as to include protein other than albumin where there has been no teaching such that one would pedict proteins that would bind to an arypropionic acid without the need for undue trial and error experimentation, for example. It is noted that applicant still has not addressed section (c) of the rejection of record.

Claims 1, 2, 7-11, 13-19, 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Hale et al.

Applicant has argued that the Hale patent fails to teach one in the art to use oligonucleotides and arylpropionic acids as claimed. It is noted however that it is not required that the anticipatory reference teach the use of the genus claimed. The reference discloses an oligonucleotide and naproxen, which is a species of the genus claimed. Applicant further argues that there is much picking and choosing from Hale et al to come up with the instantly claimed invention. However it is clear that Hale et al at at least column 38, lines 47-67 provide specific direction to include naproxen for the specific use of increasing the half-life and specifically using naproxen which binds to serum albumin, for example.

Claims 1, 2, 5-11, 13-19, 26-29, 31, 32, 39, 40, 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hale et al., Blaschke et al, Herve et al., Lagrange et al., applicant apparent admission at page 14, line 21-p. 15, line 3 of the specification and now also Blaney et al [US 5,714,142]. This rejection is the same rejection set forth in the Official Action mailed 10/03/01. The rejection was withdrawn in the Official Action mailed 7/30/02 but has been reapplied with an additional reference to the above claims after reconsideration.

The references above are all applied as per the 103 rejection of record as set forth in paper No. 8, mailed 10/3/01.

Blaney et al is applied to demonstrate that it was known in the art that there was a need to increase the serum half-life of peptides, proteins, nucleotides, oligonucleotides etc. (see column 1-2, for example). Blaney et al have taught the extension of half-life of oligonucleotides via the attachment of a selective transthyretin binding ligand. Blaney et al have also taught various modifications to oligonucleotides in the practice of there invention at column 5, for example.

In addition to the statements of motivation provided in the rejection of record it is further provided that Blaney et al clearly provide a motivation to extend the half-life of oligonucleotides and polypeptides in serum since is has been asserted by Blaney et al that was known in the art that there was such a need and it would have been obvious to extend the half-life of a peptide or oligonucleotide by the addition of arylpropionic acids that have been taught in the art or were known to bind to albumin which has been taught by the art to be an indicator of a molecule that will provide a molecule with half-life extension in serum, for example. With this motivation and teaching combined with those above it is clear that the invention as a whole would have been prima facie obvious to one in the art at the time the invention was made.

It is noted that applicant has argued (in paper No. 9, filed 1/22/02) that the rejection is improper since Hale et al provide for much picking and choosing. It is noted, however, that Hale et al at least at column 38, lines 47-67 provide specific direction to include naproxen for the specific use of increasing the half-life and specifically using naproxen which binds to serum albumin, for example. It was taught by Hale et al to use moieties such as naproxen based on their ability to bind to albumin and since it has ben

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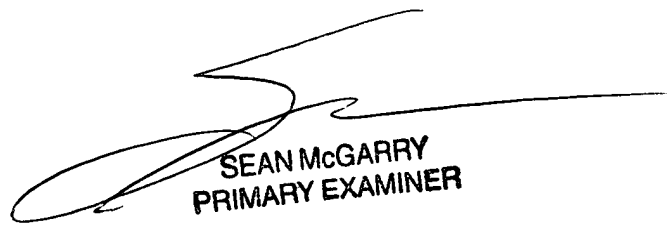
admitted by applicant that the specific arylpropionic acid recited in the claims were known to bind to albumin it follows from Hale et al that such compounds would clearly be considered as taught by Hale et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SRM
February 6, 2003


SEAN MCGARRY
PRIMARY EXAMINER
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